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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/996,128
Filing Date: November 27, 2001
Appellant(s): HOUGHTON ET AL.

Marina Larson, Ph.D.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 27, 2007 appealing from the Office action mailed December 27, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Zhai et al. "Antigen-Specific Tumor Vaccines: Development and Characterization of Recombinant Adenoviruses Encoding MART1 or gp100 for Cancer Therapy" The Journal of Immunology, Vol. 156 (January 1996), pp. 700-710.

5,773,291	BOUCHARD	06-1998
6,080,727	ZUPI	06-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

Claims 20-23, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhai et al. (The Journal of Immunology 156: 700-710, January 1996), and further in view of U.S. Patent number 5,773,291 (filed January 23, 1995/ IDS reference, submitted May 23, 2003) and U.S. Patent number 6,080,727 (effective filing date March 26, 1996). Zhai teaches a method of inducing specific T cell immunity for mammalian metastatic melanoma treatment. Several xenogenic differentiation antigens, including human melanoma-associated antigen, gp100 were expressed in recombinant adenoviruses were administered to C57BL/6 mice and rendered a protective affect against murine melanoma, see Abstract; page 707, Figure 7 and first paragraph of Discussion section; and page 708, Table IV.

Zhai does not teach a method for treating melanoma in a mammalian subject comprising administration of a human tyrosinase xenogeneic differentiation antigen or a human gp75 of the same type as the differentiation antigen expressed by melanoma cells of the said subject. However, patent '291 teaches the expression of biologically active human tyrosinase and gp75, tumor-associated antigens (TAA) within a vector,

see Abstract; and column 10, lines 41-48. And patent '727 teaches the administration of nucleotides in a method of arresting or inhibiting melanoma cancer cell proliferation in a mammal, such as a dog, see Abstract; and column 10, lines 37-49.

It would have been *prima facie* obvious at the time of the claimed invention was made to use tyrosinase or gp75 as a xenogeneic differentiation antigen to be administered in the melanoma treatment exemplified by Zhai. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because it is well known in the art that tyrosinase and gp75, quite like gp100 is recognized as a TAA implicated in the development of cancer vaccines and the Zhai treatment of mammalian metastatic melanoma was advantageous, see Zhai, page 700, abstract and column 1. Moreover, one of ordinary skill in the art would have been motivated to substitute gp100 with human tyrosinase or human gp75 in order to establish another successful mode of melanoma treatment for any mammal listed in patent '727 (including a dog), column 10, lines 37-49 because it is well established that biologically active melanoma-associated antigens are capable of being expressed.

(10) Response to Argument

Appellants assert the principle reference, Zhai, which teaches active specific immunotherapy for mammalian melanoma treatment is not applicable to the instant claimed invention because the teaching is directed to induction of an immune response in mice instead of dogs. Appellants add while Zhai does teach that mice immunized with adenovirus encoding human MART1 or gp100 were protected from tumor

challenge with B16 murine melanoma cells, this, as well as other teachings of Zhai do not render the claimed invention obvious, see Brief, page 3, 1st paragraph. Appellants allege "the Examiner has treated this teaching of one type of melanoma as a teaching of all types of melanoma, including canine malignant melanoma (CMM) as recited in claim 20." In attempt to further these arguments and differentiate between CMM and other melanomas, Appellants supply a declaration and references from Modiano, University of California at Davis and the National Canine Cancer Foundation web site that define canine malignant melanoma, see Exhibit Appendix.

The Examiner noted on page 4 of the Final Office Action mailed December 27, 2006, Zhai teaches "...a method of inducing specific T cell immunity for mammalian metastatic melanoma treatment utilizing xenogenic melanoma-associated antigen differentiation antigens expressed in recombinant adenoviruses and consequently administering said antigens to C57BL/6 mice. The administration was successful rendering a protective affect against murine metastatic melanoma." The entire Zhai reference supports their entirety, specifically the last three sentences of the abstract, as well as bridging paragraph of columns 1 and 2 of page 700 contrary to Appellants' assertions noted on page 4 of the Brief, 1st full paragraph.

The declaration notes the B16 melanoma of Zhai is not the metastatic version and asserts this type of melanoma is not a viable model for CMM and references Nicolson (Cancer Research 38: 4105-4111, November 1978 and not included in Appellants' Evidence Appendix). The purpose of Zhai was to develop a vaccine for the treatment of patients with metastatic melanoma implementing immunizing adenoviruses

encoding tumor antigens, see 2nd line of the Abstract. The experimentation relies upon the immunization of C57BL/6 mice with the said recombinant adenoviruses (established for treatment of patients with metastatic melanoma) to protect the mice challenged with murine melanoma B16. Nicolson notes there are B16 melanoma cell lines of varying *in vivo* metastatic potential, however these cell lines are "...useful for studying tumor cell and host properties associated with metastasis.", see abstract; Experimental...section on page 4105; and page 4106, column 1, 1st paragraph.

The Examiner presented in the Final Rejection and sets forth again Zhai teaches the treatment of patients with *metastatic* melanoma, not just melanoma in a broad sense (which does include both, benign and malignant cancer). The *metastatic* melanoma of Zhai is within the scope of CMM. These two states of melanoma are not mutually exclusive. While Nicolson discusses differing characteristics of the B16 cell line (low *in vivo* metastatic potential versus high *in vivo* metastatic potential), Nicolson does not unequivocally state the B16 melanoma cell line is not metastatic. Hence, Appellants have not presented sufficient evidence the B16 melanoma set forth in Zhai is not the metastatic version, as indicated in the Advisory Action mailed July 3, 2007. Given Zhai purpose's treating patients with metastatic melanoma it is reasonable for one of ordinary skill in the art to read the B16 melanoma is the metastatic type. Zhai provides evidence exemplifying the success of mammalian metastatic melanoma treatment implementing gene therapy.

Appellants further argue the Examiner's citings of U.S. Patent number 6,080,727 and U.S. Patent number 5,773,291 do not aid in establishing a *prima facie* case of

obviousness. Appellants cite "...at best [the '727 patent can] be said to provide support for the proposition that melanoma (as general term) occurs in dogs, but...the reference has nothing to do with melanoma differentiation antigens...[and] noting further can be reasonably extracted from this reference, see bridging paragraph of pages 4 and 5 of the Brief. While the patent '727 does teach the administration of nucleotides in a method of arresting or inhibiting melanoma cancer cell proliferation in a mammal, such as a dog, this does not teach away from the implementation of gene therapy for treating melanoma (term including metastatic, malignant and benign) in canines, see Abstract; and column 10, lines 37-49.

Appellants' arguments regarding patent '291 simply reflect upon the alleged misgivings of Zhai. Patent '291 teaches the expression of biologically active human tyrosinase and gp75, tumor-associated antigens (TAA) within a vector, see Abstract; and column 10, lines 41-48. The applicability of this teaching in context of the claimed invention should not be ignored. Patent '291 assures one of ordinary skill in the art of the high propensity that exists to express biological functional tumor-associated antigens (TAA). The prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Appellants' disclosure. The Examiner has met all of the criteria necessary for establishing a *prima facie* case of obviousness and accordingly the instant rejection should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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PRIMARY EXAMINER
11/26/2007

Conferees:

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